

10/611,586

3

PC9923B

**REMARKS/ARGUMENTS****Status of Claims**

Claims 1-45 and 48-50 are pending in the application.

Claims 1-45 and 48-50 are rejected in the present Office Action.

In order to expedite prosecution of the subject application, claims 1-40, 44, 45, and 48-50 have been cancelled without waiver or prejudice to filing a divisional application directed to the cancelled subject matter. Cancellation of the above claims renders the rejections to these claims moot. After entry of the amendments, claims 41- 43 are pending in the application. Accordingly, the remarks and arguments provided below are with regards to claims 41-43 only.

**Double Patenting Rejection**

Claims 41-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,641,840. The Examiner alleges that the "instant claims are broader in that they only claims a sustained release formulation for growth hormone secretagogues with a particular Cmax value without the specific components that achieve such a release profile. As such, the species, U.S. Patent No. 6,641,840 reciting the specific formulation, anticipates the genus, the instant claims reciting the generic sustained release composition." (Office Action, page 3, lines 2-8) Applicants believe that the subject matter of claims 41 -43 of the instant application is patentably distinct from that of claims 1-3 of the cited U.S. patent for the following reasons.

Claims 1-3 of the cited U.S. patent are directed to a composition of matter while claims 41-43 of the instant application are directed to a process. Specifically, as the Examiner correctly states, "U.S. Patent No. 6,641,840 claims a sustained release formulation for growth hormone secretagogues with very specific components and concentrations." In comparison, claims 41-43 of the instant application are directed to a method of increasing plasma concentration of IGF-I while minimally affecting the plasma concentration of growth hormone, which method comprises administration of a therapeutically effective amount of a growth hormone secretagogue in a sustain release formulation or a combination of a sustained release and immediate release dosage form. There is no species-genus relationship between the subject matter of claims 41-43 in the

10/611,586

4

PC9923B

instant application and that of claims 1-3 of the cited U.S. patent. Because of the above differences, the issuance of a patent from the instant application would not provide extension of the term of the right to exclude granted by the cited U.S. patent. Further, as disclosed in the instant application, "Prior to the present invention, it was not known how to prepare a therapeutic formulation containing a growth hormone secretagogue . . . which stimulated the levels of endogenous IGF-I while minimally affecting the release of GH over time." (column 2, lines 25 - 30); therefore, the claimed method of the instant application would not be obvious to a person skilled in the art in view of claims 1-3 of the cited patent. Accordingly, claims 41-43 of the instant application cannot be properly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of the cited U.S. patent.

**Claim Rejection under 35 U.S.C. §103**

Claims 41-43 are rejected under 35 U.S.C. §103 (a) as being unpatentable over Hipskind et al (U.S. Patent No. 5,773,441) in combination with Carpino et al (U.S. Patent No. 6,107,306), and further rejected over Hipskind et al in combination with Carpino et al in further combination with Devane et al (U.S. Patent No. 6,228,398). In addition, claim 41 is also rejected over Hipskind et al in combination with Carpino et al in further combination with Curatolo et al (WO 9901122) or Curatolo et al (WO 9530422). Applicants respectfully submit that a prima facie case of obviousness has not been made out, for reasons detailed below.

First, the cited references, individually or in combination, do not suggest all the limitations of the claimed invention. As explained above, claims 41-43 are directed to a method of increasing plasma concentration of IGF-1 while minimally affecting the plasma concentration of growth hormone, which method comprises administration of a therapeutically effective amount of a growth hormone secretagogue in a sustain release formulation or a combination of a sustained release and immediate release dosage form. In comparison, both Carpino and Hipskind disclose compounds as growth hormone secretagogues and various dosage forms for administering the compounds for purpose of stimulating

10/611,586

5

PC9923B

growth hormone secretion. The disclosure of WO 9901122, WO 9530422, and Devane, as the Examiner pointed out, all relate to various dosage forms. None of these references has any disclosure regarding any method of increasing the plasma IGF-I levels, or any effect for any dosage form of growth hormone secretagogues on plasma IGF-I levels with or without regards to plasma growth hormone levels.

Further, as is disclosed in the instant application, "[p]rior to the present invention, it was not known how to prepare a therapeutic formulation containing a growth hormone secretagogue . . . which stimulated the levels of endogenous IGF-I while minimally affecting the release of GH over time." (column 2, lines 25 - 30). None of the references has any suggestion on how to prepare such a therapeutic formulation either. Without such knowledge or suggestion, a person skilled in the art would have no reasonable expectation of success, nor would be motivated, to do what is claimed in claims 41-43.

Moreover, Hipkind teaches administration of growth hormone secretagogues "for the purpose of stimulating endogenous growth hormone release." (column 43, lines 10-14). Similarly, Carpino teaches administration of growth hormone secretagogues "to obtain effective release of growth hormone." (column 32, lines 2-8). Thus, both references teach how to effectively increase the growth hormone levels, which teaches away from "minimally affecting the plasma growth hormone levels," which is recited in claims 41 - 43.

10/611,586

6

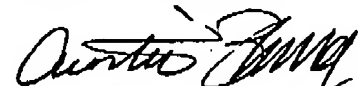
PC9923B

**Concluding Remarks**

In view of the above amendments and remarks, Applicants respectfully request reconsideration of the application, withdrawal of the rejections, and timely issuance of Notice of Allowance.

Respectfully submitted,

Dated: 10/25/04



Austin W. Zhang  
Registration No. 48,061  
Warner-Lambert Company LLC  
2800 Plymouth Road  
Ann Arbor, MI 48105  
Telephone: (734) 622-5035  
Facsimile: (734) 622-1553